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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL E. MOSELEY and
JOHN KUCHARCZYK

Appeal 2010-009722
Application 09/606,137
Technology Center 3700

Before ERIC GRIMES, STEPHEN WALSH, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of determining the viability of transplanted cells, which the Examiner has rejected as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that "[a]s cells are introduced into a tissue for purposes of effecting therapy to a patient, it becomes critical to monitor the

status of the cells and their assimilation and integration into the environment" (Spec. 15:11-13). The Specification states that certain "hallmarks of cell growth and proliferation . . . can be assessed according to the present invention (as by MRI)," such as indications of increased metabolism as the cells replicate or the presence of or increase in blood flow (*id.* at 15:13-31).

Claims 5-7, 9, 11-26, 29, and 54-59 are on appeal.[1] Claim 59 is the broadest independent claim and reads as follows:

59. A method for indicating viability of transplanted progenitor or stem cells, the method being performed with a medical device that supports at least one sensing function, the method comprising:

non-destructively observing a region of a patient to where progenitor or stem cells have been transplanted;

sensing a property within said region of a patient that is indicative of cell viability or inviability of transplanted progenitor or stem cells; and

using data from sensing said property within said region to indicate cell viability from a transplant of progenitor or stem cells within the region wherein said cell viability is indicated by a property in cell chemistry resulting from an event selected from the group consisting of cell activity, cell inactivity, cell growth, cell death, specific cell function, specific cell dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population.

The claims stand rejected as follows:

- Claims 5, 6, 13, 14, 17, 18, 20, 21, 25, 26, 54, 55, 57, and 59 under 35 U.S.C. § 102(b) as anticipated by Major[2] (Answer 3);

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[1] The Claims Appendix of the Appeal Brief also includes claims 60-64 but Appellants have stated that these claims are not on appeal and should be treated as canceled (Special Communication filed Nov. 5, 2009, second page).

• Claims 7, 9, 11, 12, 15, 16, 19, 22, 29, 56, and 58 under 35 U.S.C. § 103(a) as obvious based on Major and Morcos[3] (Answer 4);

• Claim 23 under 35 U.S.C. § 103(a) as obvious based on Major and Chenevert[4] (Answer 5); and

• Claim 24 under 35 U.S.C. § 103(a) as obvious based on Major and Dinsmore[5] (Answer 6).

All of the pending claims stand rejected as anticipated by Major or obvious based on Major and an additional reference. The same issue is dispositive with respect to all of the rejections.

The Examiner finds that Major discloses a method of indicating the viability of transplanted cells that

> involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36).

(Answer 3.)

Appellants argue that Major does not disclose non-destructively observing a region containing transplanted cells and sensing a property in cell chemistry that indicates cell viability, as required by the claims (Appeal Br. 17-18). Specifically, Appellants argue that Major tests cells in vitro for viability before implantation (*id.* at 18-19) but monitors successful engraftment of cells only by post-mortem histological methods, not the

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[2] Major et al., US 5,869,463, Feb. 9, 1999
[3] Morcos et al., US 5,497,770, Mar. 12, 1996
[4] Chenevert et al., US 6,567,684 B1, May 20, 2003
[5] Dinsmore, US 6,140,116, Oct. 31, 2000

claimed method of non-destructively observing a tissue region (*id.* at 19-20). Appellants argue that Major's only uses of MRI are to initially position the transplanted tissue in the subjects (*id.* at 20) and to assess tumor formation (*id.* at 19), not to sense a property indicative of cell viability. Appellants also argue that the additional references cited in the rejections under § 103 do not make up for the deficiency of Major (*id.* at 25-27).

We agree with Appellants that the Examiner has not adequately shown that Major discloses a method that includes all of the limitations of the claims on appeal, or that Major in combination with any of the other cited references would have made obvious a method meeting the limitations of the rejected claims. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

All of the claims on appeal require "non-destructively observing a region of a patient" where cells have been transplanted, sensing a property that is indicative of cell viability, and using the sensed property to indicate cell viability, where cell viability is indicated by a property in cell chemistry (*see, e.g.*, claim 59). One method of non-destructively observing a tissue region is by MRI (Spec. 15:13-14).

The Examiner points to Major's disclosure at column 7, lines 33-41, and column 11, lines 28-36, as meeting the "non-destructively observing" and "sensing" limitations of the claims (Answer 3). These passages, however, do not describe the steps required by the claims. At column 7, lines 33-41, Major describes performing "pre-implantation MRI" to determine target coordinates for the later implantation of cells in the

subject's brain. This disclosure therefore does not describe "non-destructively observing a region of a patient to where progenitor or stem cells *have been* transplanted" (claim 59, emphasis added).

At column 11, lines 28-36, Major describes using MRI to evaluate tumor or nodule formation in monkeys following implantation of cells. Major discloses that the "scans revealed no evidence of tumor or nodule formation" (Major, col. 11, ll. 35-36) but does not describe the results as indicating anything about the viability of the transplanted cells. The Examiner has not provided evidence that detecting "no evidence of tumor formation" (*id.* at col. 11, l. 30) is the same thing as "sensing a property . . . that is indicative of cell viability or inviability," as recited in the claims. That is, the lack of tumor evidence described in Major does not indicate either viability or inviability of the transplanted cells.

Thus, the Examiner has not shown that Major discloses a method meeting the limitations of the claims on appeal. The Examiner has not pointed to any disclosure in Morcos, Chenevert, or Dinsmore that would have made obvious the limitations that are not expressly disclosed by Major, and therefore has also failed to establish a prima facie case of obviousness.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED

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